

Bictegravir/Emtricitabine/Tenofovir Alafenamide (B/F/TAF) for the Treatment of People Living With HIV: 24-Month Analyses by Age, Race, Sex, Adherence and Late Diagnosis in a Multi-Country Cohort Study

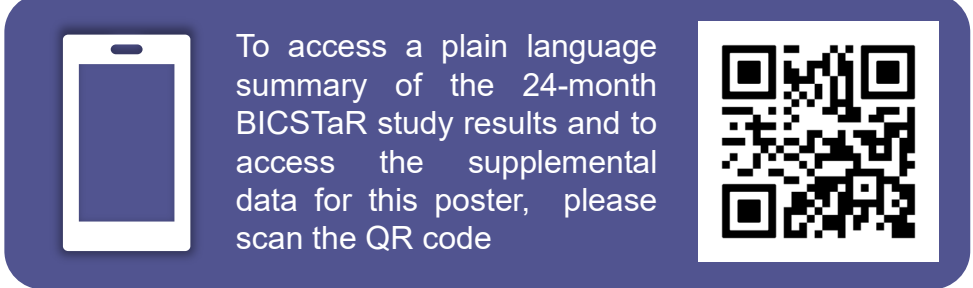
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Poster number P067



Introduction

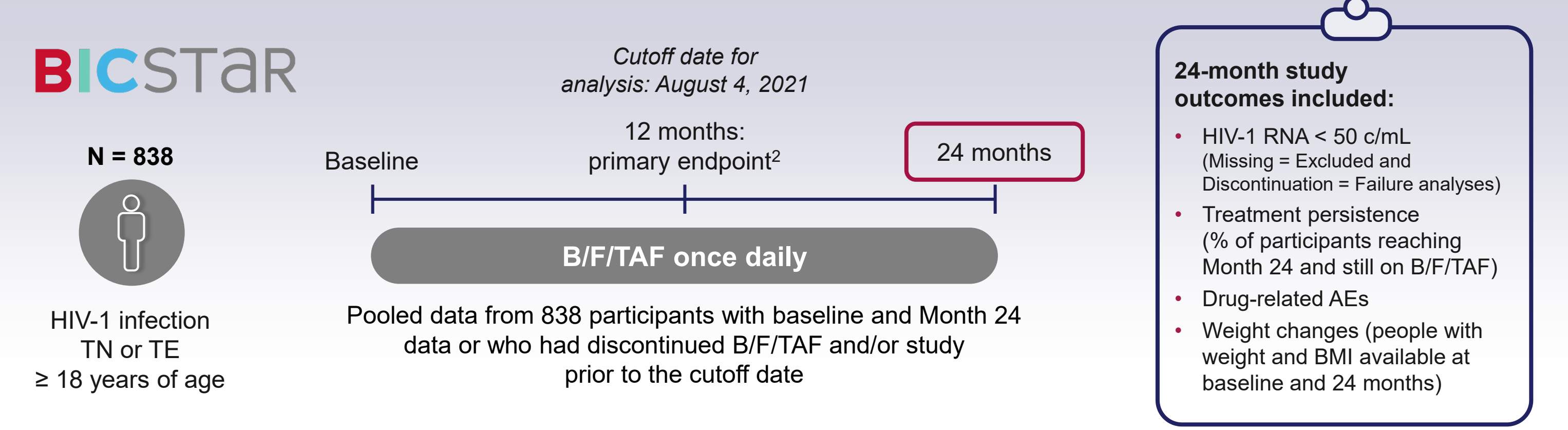
- B/F/TAF is a guideline-recommended single-tablet regimen for the treatment of HIV-1 infection that can contribute to long-term treatment success in people living with HIV¹
- BICSTaR is a large, ongoing, multi-country, prospective, observational study that has enrolled 2,380 ARV treatment-naïve (TN) and treatment-experienced (TE) people in Europe (France, Germany, Ireland, Italy, the Netherlands, Spain, UK), Canada, Israel, Japan, Taiwan, South Korea and Singapore

Methods

- In this planned analysis with a data cutoff of August 4, 2021, **pooled 24-month effectiveness and safety** data are presented for people receiving B/F/TAF in routine clinical care from France, Germany, Ireland, Italy, the Netherlands, Spain, UK, Canada and Israel
- We describe data both in the overall population and in key groups related to sex, age, race, treatment adherence level, late diagnosis and prior use of TDF (for weight only)*

*With exception of individuals with a late diagnosis, key group analyses were restricted to the TE participants due to the small numbers in the TN group

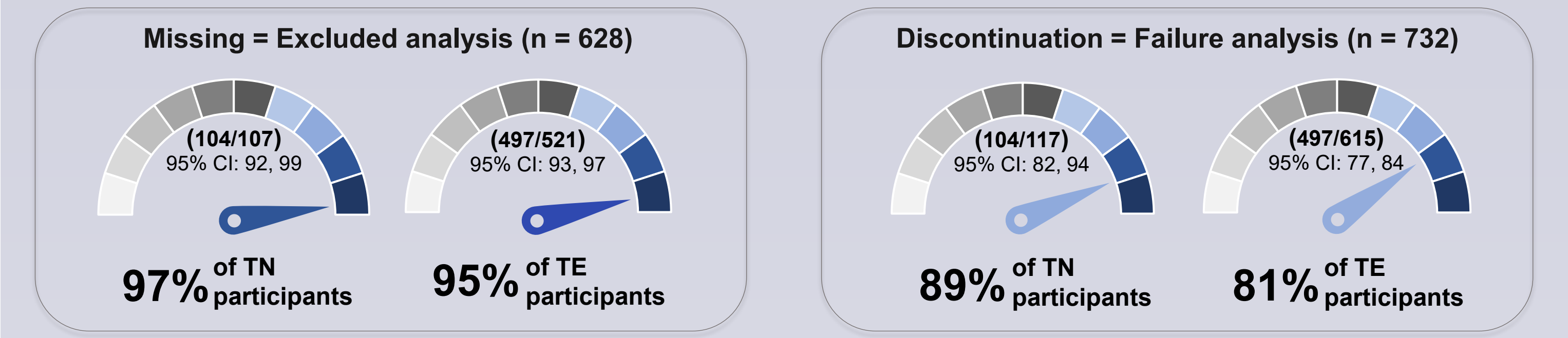
Study Design



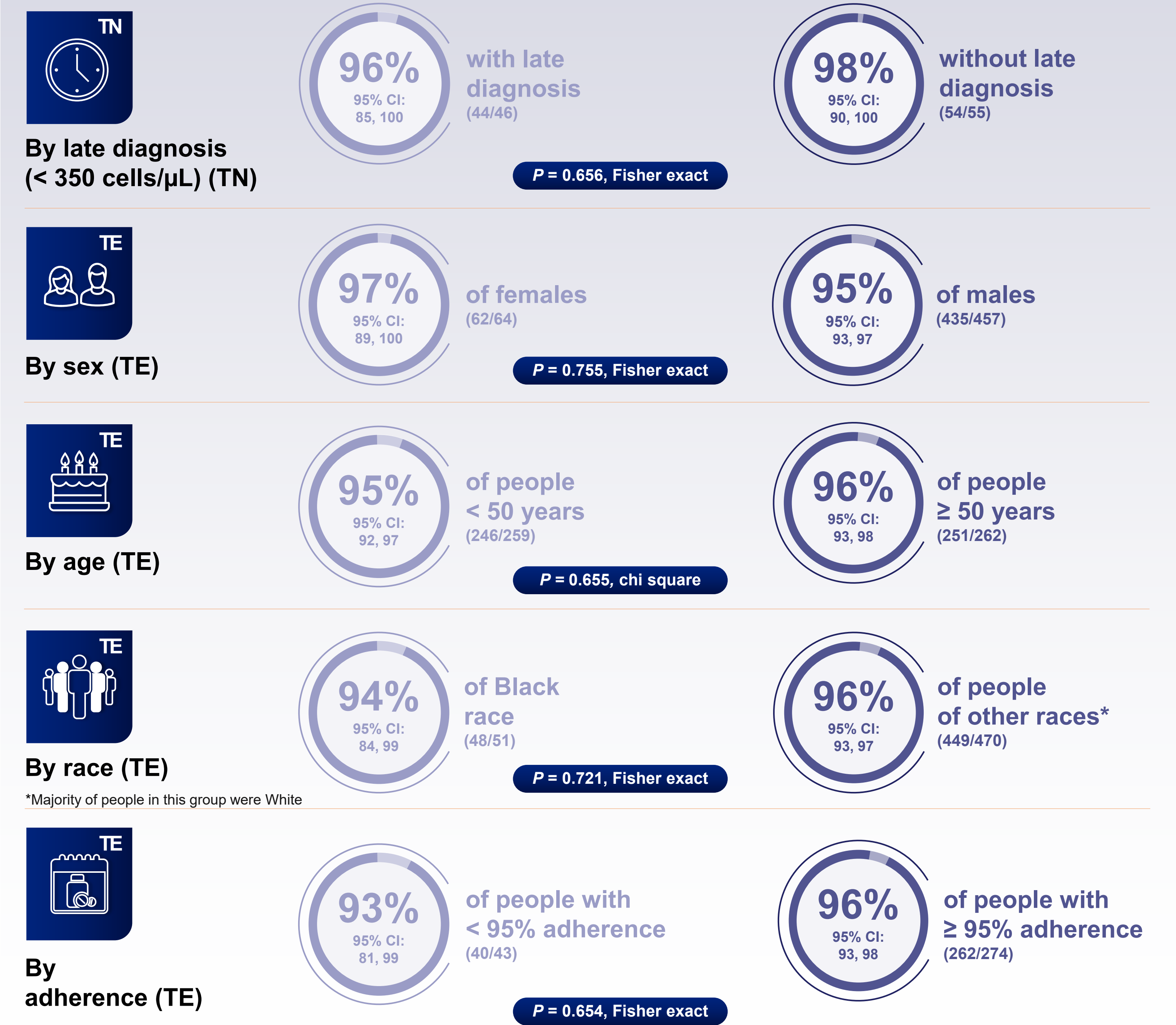
Conclusions

- B/F/TAF showed high effectiveness and persistence after 24 months in a cohort of people living with HIV in routine clinical care
- Together with clinical trial data, these real-world data continue to support the broad use of B/F/TAF in both treatment-naïve and treatment-experienced individuals

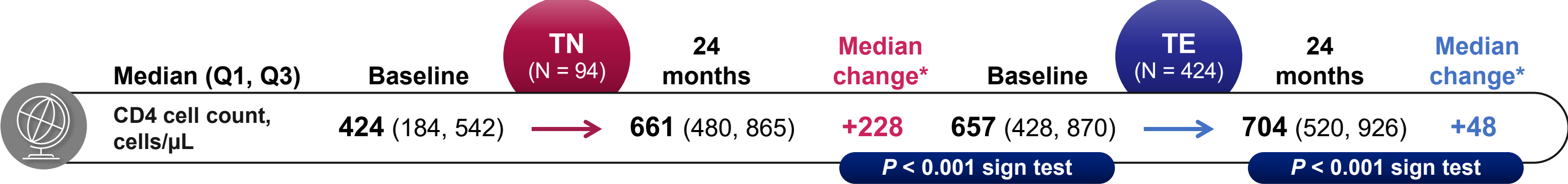
Effectiveness: % HIV-1 RNA < 50 c/mL at 24 Months – Overall Population



Effectiveness: % HIV-1 RNA < 50 c/mL at 24 Months – Key Groups

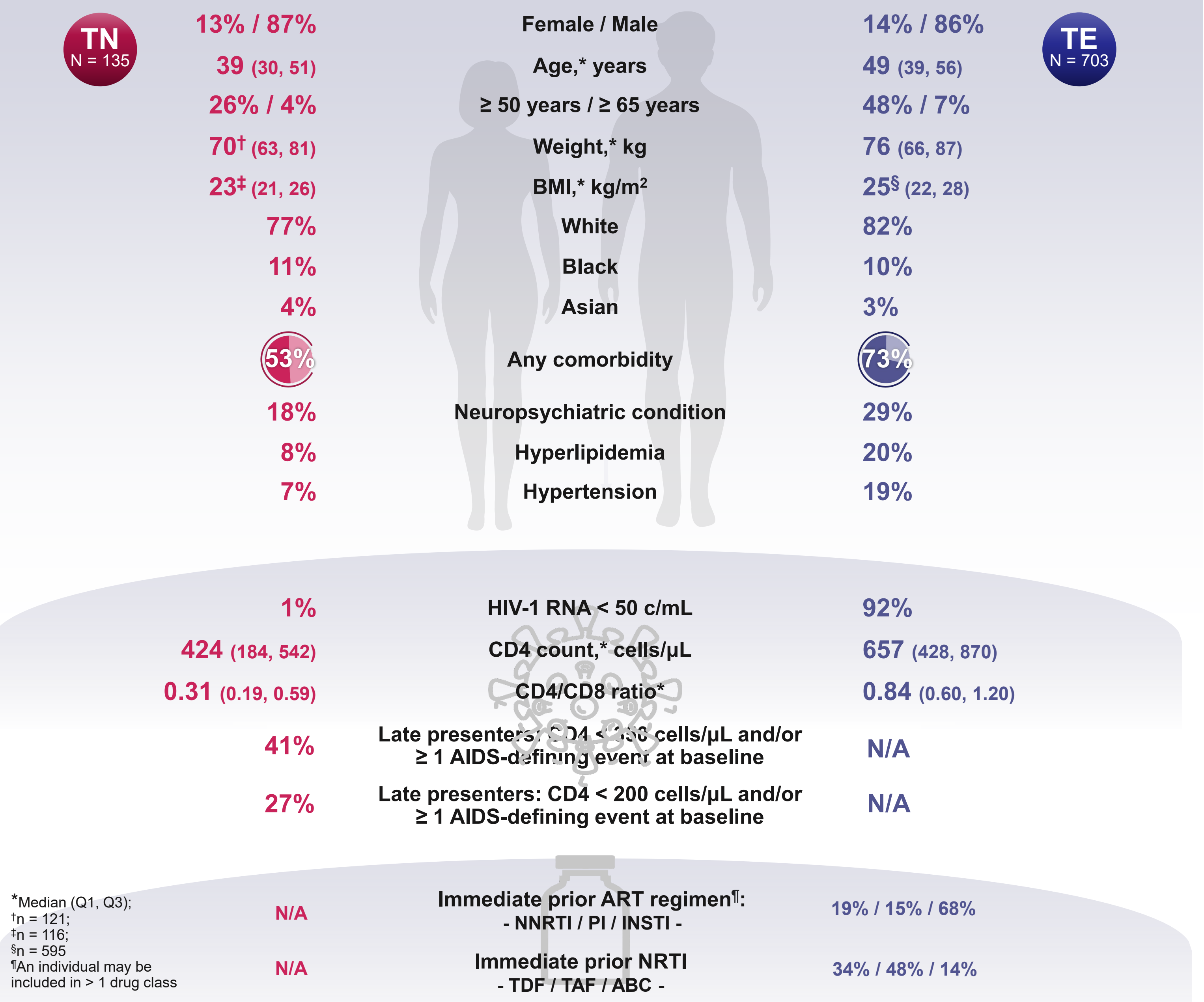


Change from Baseline in CD4 Cell Count at 24 Months – Overall Population

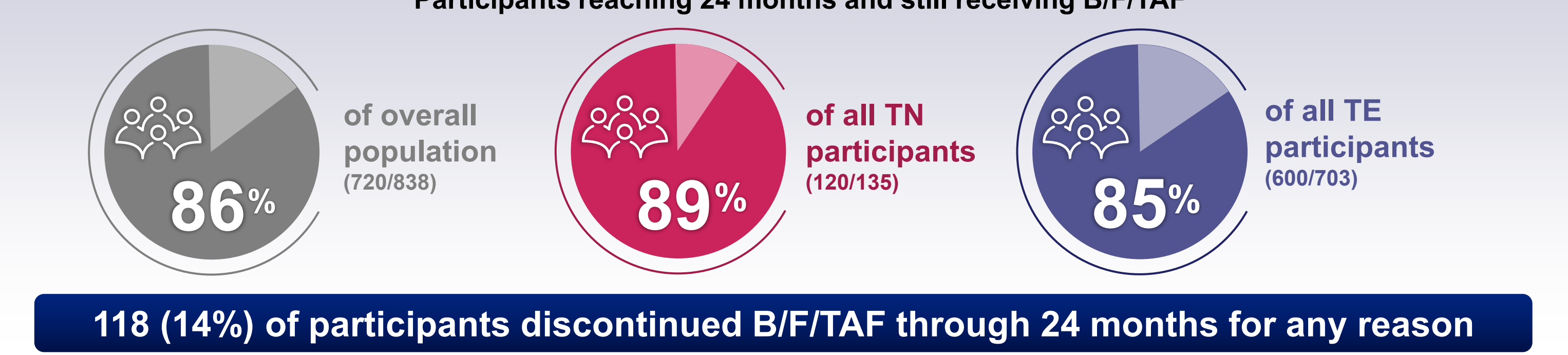


*Calculated as changes from baseline to 24 months for each individual participant

Baseline Characteristics



Persistence



Key Safety Data Through 24 Months

Overall population (N = 838)	By sex (TE)		By age (TE)	
	Female (n = 96)	Male (n = 607)	< 50 y (n = 369)	≥ 50 y (n = 334)
128 (15%)* with DRAE(s)	15 (16%)	89 (15%)	61 (17%)	43 (13%)
2† (< 1%) serious DRAEs	0	2 (< 1%)	1 (< 1%)	1 (< 1%)
62 (7%)* discontinued B/F/TAF due to DRAEs‡	9 (9%)	45 (7%)	31 (8%)	23 (7%)

*TN: 18% (24/135), TE: 15% (104/703); †Both in the TE group; ‡TN: 6% (8/135), TE: 8% (54/703); §Most commonly weight increase (3%) and depression (1%); ¶Chi square and Fisher exact tests for the difference between groups: the null hypothesis was that there were equal proportions in the two groups

Weight (kg) – Overall and Key Groups

	Median (Q1, Q3)	Baseline	TN (N = 75)*	24 months	Median change†	Baseline	TE (N = 376)*	24 months	Median change†
 Overall	69 (63, 80)	→	75 (68, 84)	+4.3¶ (0, 9)	76 (67, 87)	→	77 (69, 89)	+1.2¶ (-1.0, 4.5)	
 By baseline CD4	68 (63, 72)	→	73 (70, 83)	+6.6¶ (1.4, 10.0)	70 (62, 80)	→	79 (67, 84)	+4.0¶ (-0.3, 8.0)	
 By sex	65 (59, 74)	→	65 (58, 78)	+0.5 (-1.6, 3.0)	78 (69, 88)	→	79 (70, 90)	+1.3¶ (-1.0, 4.8)	
						P = 0.150 Wilcoxon test‡§			
 By age	76 (66, 86)	→	77 (68, 88)	+1.5¶ (-0.9, 4.7)	77 (68, 87)	→	78 (70, 89)	+1.0¶ (-1.0, 4.3)	
						P = 0.324 Wilcoxon test‡§			
 By race	72 (65, 85)	→	74 (66, 86)	+0.9 (-1.0, 4.3)	77 (67, 87)	→	78 (69, 89)	+1.2¶ (-1.0, 4.5)	
 By prior TDF	77 (67, 87)	→	78 (69, 90)	+1.0¶ (-1.0, 4.5)	74 (67, 86)	→	77 (68, 88)	+2.0¶ (0.0, 4.3)	

*Population with weight and BMI data available at baseline and 24 months; †Calculated as changes from baseline to 24 months for each individual participant; ‡People of other races, of which the majority were White; §Non-parametric test null hypothesis was that there were equal median changes in the two subgroups; ¶P < 0.05 for change from baseline in group using the sign test (null hypothesis that there was zero change from baseline)

References
1. Panel on Antiretroviral Guidelines for Adults and Adolescents. <https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/adult-adolescent-arv/guidelines-adult-adolescent-arv.pdf> (accessed Jul 22, 2022).
2. Malloias J, et al. EACS 2021, Poster PE2/57
Abbreviations
AE, adverse event; ART, antiretroviral treatment; ARV, antiretroviral; BICSTaR, Bictegravir Single Tablet Regimen; B/F/TAF, bictegravir/emtricitabine/tenofovir alafenamide; DRAE, drug-related adverse event; INSTI, integrase strand transfer inhibitor; N/A, non-applicable; NNRTI, non-nucleoside reverse transcriptase inhibitor; NRTI, nucleoside reverse transcriptase inhibitor; PI, protease inhibitor; TDF, tenofovir disoproxil fumarate; TE, treatment-experienced; TN, treatment-naïve
Acknowledgments
We thank all study participants. The BICSTaR study is sponsored by Gilead Sciences. Medical writing support was provided by Emma McConnell, PhD, and Olivia Morris, PhD (Aspire Scientific Ltd), and funded by Gilead.
Disclosures
BICSTaR is sponsored by Gilead (GS-EUC-380-4472/GS-CA-380-4574/GS-IL-380-5335). Please see the supplement for author disclosures.